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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,835

02/07/2005

Francis Ignatious

P51366

2405

20462

7590

03/25/2009

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EXAMINER

PHILLIPS JR, WELDON P

ART UNIT

PAPER NUMBER

4121

NOTIFICATION DATE

DELIVERY MODE

03/25/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,835	<b>Applicant(s)</b> IGNATIUS ET AL.	
	<b>Examiner</b> WELDON PHILLIPS JR.	<b>Art Unit</b> 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application for patent, filed, entered the national stage in the United States of America on February 7, 2005 under 35 USC 371 from PCT/US2003/24641, filed August 7, 2003, claiming priority from U.S. Provisional Application No. 60/401,726, filed August 7, 2002.

Claims 1-46, as amended, are now pending.

### ***Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a "single general inventive concept" as required under PCT Rule 13.1 and 37 C.F.R. § 1.475(a). In accordance with 37 CFR § 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I:** Claims 1-27, 39 and 46, drawn to compositions;

**Group II:** Claims 28-38, drawn to methods of making; and

**Group III:** Claims 40-45, drawn to methods of making.

2. As set forth in PCT Rule 13.1, the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). As stated in Rule 13.2, where a group of inventions is claimed in an international application, the requirement of unity of

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invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Rule 13.2 defines special technical features as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. A lack of unity of invention determination begins with a consideration of the claims in light of the description and drawings. Lack of unity of invention may be directly evident "a priori," or before considering any prior art when no special technical feature is common to each of the independent claims. Alternatively, lack of unity of invention may only become evident "a posteriori," or after considering the claims in relation to the prior art.

3. In the instant application, the claimed inventions listed as Groups I, II and III are not so linked as to form a "single general inventive concept" under PCT Rule 13.1 and 37 C.F.R. § 1.475(a), because they lack the same or corresponding special technical features. The technical feature shared by Groups I, II and III is an electrospun fiber comprising a pharmaceutically acceptable polymer and an amorphous form of a pharmaceutically active agent. The method of claim 28 does not present a contribution over claim 24 of Ignatious (WO 01/54667). As such, Group II does not share a special technical feature with the instant claims of Groups I and III, the claims are not so linked within the meaning of PCT Rule 13.2 as to form a single inventive concept over the prior art, and unity between Groups I, II and III is broken. Because unity of invention is

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lacking, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

4. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined** even though the requirement may be traversed under 37 CFR § 1.143 **and (ii) identification of the claims encompassing the elected invention**, including any claims subsequently added.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR § 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the claimed inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the claimed inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the claimed inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other claimed inventions.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance

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with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Elections of Species***

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**If Group I is elected**, EACH of the following species elections is required:

- a) Elect for the polymeric carrier(s) present in the composition (e.g., Eudragit L100-55, etc.);
- b) Elect for a single active agent present in the composition (e.g., aspirin, etc.); and
- c) Elect for the presence or absence of a surfactant in the composition and, if present, elect for the surfactant(s) (e.g., ethylene oxide, etc.).

**If Group II is elected**, EACH of the following species elections is required:

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- a) Elect for the polymeric carrier(s) present in the composition (e.g., Eudragit L100-55, etc.);
- b) Elect for a single active agent present in the composition (e.g., aspirin, etc.), and
- c) Elect for a pharmaceutically acceptable solvent (e.g., ethanol, etc.)

**If Group III is elected**, EACH of the following species elections is required:

- a) Elect for the polymeric carrier(s) present in the composition (e.g., Eudragit L100-55, etc.); and
- b) Elect for a single active agent present in the composition (e.g., aspirin, etc.).

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, as to claims 1-27, 39 and 46 of Group I, applicant is required to elect for the polymeric carrier(s), a single active and surfactant(s), if present, in the composition. As to claims 28-38 of Group II, applicant is required to elect for the polymeric carrier(s), a single active agent present in the formulation and pharmaceutically acceptable solvent(s). As to claims 40-45 of Group III, applicant is required to elect for the polymeric carrier(s) and a single active agent present in the formulation. **Upon applicant's election of species, each result must provide a single chemical compound species.** The reply must also identify the claims readable on the elected species, including any claims



subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The following claim(s) are generic: claims 1-8, 11, 12, 18-27, 39 and 46 as to Group I, claims 28-30 as to Group II and claim 40 as to Group III.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

- a) Each chemical species is a distinct chemical with distinct chemical moieties.

10. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed under 37 CFR § 1.143 **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

An election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR § 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WELDON PHILLIPS JR. whose telephone number is (571)-270-7673. The examiner can normally be reached Monday through Thursday &

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every other Friday between 7:30 AM and 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WP/

Examiner, Art Unit 4121

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4121